

Notice of Allowability

Application No.

09/419,545

Examiner

S. Devi, Ph.D.

Applicant(s)

DARJI ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' amendment filed 03/30/06.
2. ☒ The allowed claim(s) ~~is/are~~ 1-6, 9, 10 and 17-23, renumbered as claims 1-6, 7, 8 and 9-15 respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 033006
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☒ Other Page 1 of pap. 20.

ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 03/30/06 in response to the non-final Office Action mailed 09/28/05.

Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Lynn Janulis in a telephonic interview on 2 June 2006.

This application has been amended as indicated below:

Claim 1 has been amended as indicated below.

--Claim 1. (Currently amended). An attenuated *Salmonella* strain comprising a eukaryotic expression vector, wherein said vector comprises ~~comprising~~ a eukaryotic promoter and a heterologous DNA encoding a heterologous polypeptide, wherein said DNA is under the control of said eukaryotic promoter, wherein the attenuation is suitable for administration to a vertebrate, and wherein said administration to said vertebrate ~~with~~ of said attenuated *Salmonella* strain results in expression of said polypeptide by said vertebrate and generates an immune response by said vertebrate to said polypeptide.--

Status of Claims

- 3) Claims 1, 3, 5, 6, 9, 19, 20 and 23 have been amended via the amendment filed 03/30/06. Claim 1 has been amended via this Examiner's amendment. Claims 1-6, 9, 10 and 17-23 are pending and are under examination.

Information Disclosure Statement

- 4) Acknowledgment is made of Applicants' information disclosure statement filed 03/30/06. The information referred to therein has been considered and a signed copy is attached to this Office Action.

The Weiss Declaration

- 5) Acknowledgment is made of Applicants' submission the Weiss Declaration filed

03/30/06 under 37 C.F.R § 1.132. The Declaration provides the publications of Branstrom (US 5,824,538) and Sizemore *et al.* (*Science* 270: 299-302, 1995) and states that the belief in the state of the prior art at the time of the filing of the instant application, was that *Salmonella*, *Salmonella typhimurium* in particular, is inefficient for DNA delivery, because it reaches the cytoplasm only with difficulty.

Rejection(s) Withdrawn

- 6)** The rejection of claim 1 and those dependent therefrom made in paragraph 15 of the Office Action mailed 09/28/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim and the amendment to the claim made via this Examiner's amendment.
- 7)** The rejection of claim 20 made in paragraph 16(a) of the Office Action mailed 09/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 8)** The rejection of claim 1 made in paragraph 16(b) of the Office Action mailed 09/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 9)** The rejection of claim 3 made in paragraph 16(c) of the Office Action mailed 09/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 10)** The rejection of claim 5 made in paragraph 16(d) of the Office Action mailed 09/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 11)** The rejection of claim 6 made in paragraph 16(d) of the Office Action mailed 09/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 12)** The rejection of claim 19 made in paragraph 16(f) of the Office Action mailed 09/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 13)** The rejection of claims 9 and 23 made in paragraph 16(g) of the Office Action mailed

09/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claims 2-6, 9, 10 and 17-23 made in paragraph 16(h) of the Office Action mailed 09/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

15) The rejection of claims 1, 2, 4, 6, 9, 10 and 17-22 made in paragraph 18 of the Office Action mailed 09/28/05 under 35 U.S.C § 102(e)(2) as being anticipated by Powell *et al.* (US 5,877,159, filed 05/03/1995 – Applicants' IDS), is withdrawn in light of Applicants' arguments and evidence supplied via the Weiss Declaration. See paragraph 4 above.

16) The rejection of claim 3 made in paragraph 19 of the Office Action mailed 09/28/05 under 35 U.S.C § 103(a) as being unpatentable over Powell *et al.* (US 5,877,159, filed 05/03/1995 – Applicants' IDS) ('159) as applied to claims 2 and 1, and further in view of Fouts *et al.* (*Vaccine* 13: 1697-1705, 1995, already of record), is withdrawn in light of Applicants' arguments and evidence supplied via the Weiss Declaration. See paragraph 4 above.

17) The rejection of claim 5 made in paragraph 20 of the Office Action mailed 09/28/05 under 35 U.S.C § 103(a) as being unpatentable over Powell *et al.* (US 5,877,159, filed 05/03/1995 – Applicants' IDS) as applied to claim 1 above, and further in view of Dyall-Smith *et al.* (US 5,332,658), is withdrawn in light of Applicants' arguments and evidence supplied via the Weiss Declaration. See paragraph 4 above.

Remarks

18) Claims 1-6, 9, 10 and 17-23 are allowed. Claims 9, 10 and 17-23 are now renumbered as claims 7, 8 and 9-15 respectively.

The limitation 'heterologous' DNA in the amended claim 1 has descriptive support at line 8 of page 4 of the specification as originally filed.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

20) Information regarding the status of an application may be obtained from the Patent

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Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

21) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

June, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER